K090242

5. 510(k) Summary

5.1 510(k) Summary – Beta-bsm

FEB 20 2009

Submitter: ETEX Corporation
38 Sidney Street
Cambridge, MA 02139
Registration No.: 1225112
Owner/Operator No.: 9014709

Contact Person: Christopher Klaczyk
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Date Prepared: January 30, 2009

Product Code(s): MQV (21 CFR 888.3045)

Device Class: II (21 CFR 888.3045)

Classification Panel: Orthopaedics

FDA Panel Number: 87

Classification Name: Filler, Bone Void, Calcium Compound (21 CFR 888.3045)

Proprietary Name: Beta-bsm Injectable Bone Substitute Material

Predicate Device(s): Beta-bsm Injectable Bone Substitute Material (cleared as OssiFuse Bone Substitute Material, K072355)
α-BSM (K072636)

Device Description: Beta-bsm Injectable Bone Substitute Material is a synthetic, biocompatible bone graft substitute material. At the time of use, the powder component is combined with a specified volume of mixing solution and mixed to form a paste. Mixing is facilitated by a syringe-to-syringe mixing system. The resulting paste can be administered to the treatment site by injection or manual application. The material can be shaped into a desired form *in-situ* prior to implantation. After the paste is applied to the treatment site, it hardens at body temperature and converts to an apatitic calcium phosphate material. The end product,

poorly crystalline hydroxyapatite (PCHA), is of low crystalline order with a similar chemical and crystalline structure to that of natural bone minerals. Beta-bsm Injectable Bone Substitute Material is an osteoconductive material that is resorbed and replaced by natural bone over time.

Intended Use: Beta-bsm Injectable Bone Substitute Material is an implantable bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (such as the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Beta-bsm Injectable Bone Substitute Material is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Materials: Synthetic calcium phosphate

Performance Data: Regression testing consistent with *Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA Staff* (dated June 2, 2003) has been submitted to show that the proposed changes to the predicate devices do not affect the risk profile of the devices.

5.2 510(k) Summary – Gamma-bsm

Submitter:
ETEX Corporation
38 Sidney Street
Cambridge, MA 02139
Registration No.: 1225112
Owner/Operator No.: 9014709

Contact Person:
Christopher Klaczyk
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Date Prepared: January 30, 2009

Product Code(s): MQV (21 CFR 888.3045)

Device Class: II (21 CFR 888.3045)

Classification Panel: Orthopaedics

FDA Panel Number: 87

Classification Name: Filler, Bone Void, Calcium Compound (21 CFR 888.3045)

Proprietary Name: Gamma-bsm Moldable Bone Substitute Material

Predicate Device(s): Gamma-bsm Moldable Bone Substitute Material (cleared as CaP_3 Bone Void Filler, K033138)
α-BSM (K072636)

Device Description: Gamma-bsm Moldable Bone Substitute Material is a synthetic, biocompatible bone graft substitute material. At the time of use, the powder component is combined with a specified volume of mixing solution and mixed to form a putty. The resulting putty is administered to the treatment site by manual application. The material can be shaped into a desired form *in-situ* prior to implantation. After the putty is applied to the treatment site, it hardens at body temperature and converts to an apatitic calcium phosphate material. The end product, poorly crystalline hydroxyapatite (PCHA), is of low crystalline order with a similar chemical and crystalline structure to that of natural bone minerals. Gamma-bsm Moldable Bone Substitute

Material is an osteoconductive material that is resorbed and replaced by natural bone over time.

Intended Use: Gamma-bsm Moldable Bone Substitute Material is an implantable bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (such as the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Gamma-bsm Moldable Bone Substitute Material is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Materials: Synthetic calcium phosphate

Performance Data: Regression testing consistent with *Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA Staff* (dated June 2, 2003) has been submitted to show that the proposed changes to the predicate devices do not affect the risk profile of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ETEX Corporation
% Mr. Christopher Klaczyk
Regulatory Affairs Manager
38 Sidney Street, 3 Floor The Clark Building
Cambridge, Massachusetts

FEB 20 2009

Re: K090242
Trade/Device Name: Beta-bsm Injectable Bone Substitute Material
Gamma-bsm Moldable Bone Substitute Material
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: January 30, 2009
Received: February 2, 2009

Dear Mr. Klaczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications For Use

4.1 Indications For Use – Beta-bsm

510(k) Number (if known): _____

Device Name: Beta-bsm Injectable Bone Substitute Material
(originally cleared as OssiFuse Bone Substitute Material)

Indications for Use:

Beta-bsm Injectable Bone Substitute Material is an implantable bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (such as the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Beta-bsm Injectable Bone Substitute Material is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090242

4.2 Indications For Use – Gamma-bsm

510(k) Number (if known): _____

Device Name: Gamma-bsm Moldable Bone Substitute Material
(originally cleared as CaP_3 Moldable Bone Void Filler)

Indications for Use:

Gamma-bsm Moldable Bone Substitute Material is an implantable bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (such as the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Gamma-bsm Moldable Bone Substitute Material is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K090242